



## 2003 ASSEMBLY BILL 355

May 22, 2003 - Introduced by Representatives UNDERHEIM, COGGS, PETROWSKI, POCAN, KRUSICK, OLSEN, A. WILLIAMS, ZEPNICK, YOUNG, TURNER, MUSSER, SINICKI, MILLER, BALOW and ALBERS, cosponsored by Senators BROWN, CARPENTER, CHVALA and HANSEN. Referred to Committee on Health.

1     **AN ACT** *to renumber and amend* 450.02 (2); *to amend* 20.435 (8) (mb), 20.435  
2           (8) (mb), 49.68 (3) (b), 49.683 (2), 49.685 (2), 49.688 (7) (a), 49.692 (6), 146.93 (1)  
3           (a) and 149.143 (1) (a); *to repeal and recreate* 49.45 (49); and *to create* 20.435  
4           (4) (jg), 20.435 (4) (jh), 20.435 (4) (jt), 20.435 (4) (jx), 40.03 (6) (k), 49.69, 49.692,  
5           149.14 (4c) (c), 441.16 (7), 447.08, 448.075, 450.02 (2) (b) and 450.075 of the  
6           statutes; **relating to:** prescription drugs, providing an exemption from  
7           emergency rule procedures, granting rule-making authority, making  
8           appropriations, and providing penalties.

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### ***Analysis by the Legislative Reference Bureau***

Currently, prescription drugs are a covered benefit under the Medical Assistance Program and BadgerCare and under the Health Insurance Risk-Sharing Program (HIRSP). Certain elderly persons are eligible to receive state assistance in purchasing prescription drugs under the program commonly known as Senior Care. Also, the state provides assistance to certain persons who have kidney disease, cystic fibrosis, or hemophilia to cover health care costs, which may include the cost of prescription drugs, under what are commonly referred to as "disease aids programs."

Drug manufacturers are required under federal law to pay rebates on prescription drugs that are purchased under state medical assistance programs.

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Federal law further requires that, with several exceptions, the price for prescription drugs purchased under state medical assistance programs, after the rebate, must be the lowest price for which the manufacturer sells its prescription drugs. Manufacturers must also pay rebates on prescription drugs purchased under BadgerCare and Senior Care, and in some cases, under the disease aids programs.

Also under current law, the secretary of health and family services is required to appoint a Prescription Drug Prior Authorization Committee (the Committee) that is responsible for advising the Department of Health and Family Services (DHFS) on prior Medical Assistance authorization policies for prescription drugs.

***Preferred drug lists***

This bill requires DHFS to create two preferred drug lists (PDLs). PDL I is for state-supported health care assistance programs (Medical Assistance, BadgerCare, Senior Care, HIRSP, Wisconcare, and several disease aids programs). PDL II is for health care plans provided to state and local government employees, health care plans provided by private employers to their employees, health care plans negotiated on behalf of a group of persons who purchase their own health insurance, for example through a trade association, and for the Prescription Drug Assistance Program created under the bill (described below).

***Creation of the PDLs.*** DHFS must use the following process to create the PDLs:

1. The Committee must determine the relative clinical efficacy and safety of prescription drugs within a therapeutic class (a group of drugs that are used to treat the same disease or medical condition).

2. DHFS must solicit offers from drug manufacturers to pay a rebate on a prescription drug if it is included on a PDL. Manufacturers may offer a different rebate amount for the two PDLs. The rebate amount for PDL I must be in addition to any rebate amount currently paid under the Medical Assistance Program.

3. DHFS must identify one or more prescription drugs within each therapeutic class that are the most cost-effective and place them on a PDL. DHFS must consider the Committee's determinations of relative clinical efficacy and safety and the cost of each prescription drug in determining cost-effectiveness. In assessing cost, DHFS must consider any manufacturer rebates that are paid under current law or current rebate agreements and any additional rebates offered in response to DHFS solicitations under this bill. Although the determinations regarding relative clinical efficacy and safety of drugs will be the same for the creation of both PDLs, the current and additional rebate amounts may differ, so the drugs identified as most cost-effective may differ between the two PDLs.

4. The bill requires DHFS to enter into agreements with manufacturers to pay the rebates offered under the bill on those drugs that are placed on a PDL and purchased under a program or health insurance plan for which the PDL is used.

5. The bill requires DHFS to place all prescription drugs that are safe and clinically effective for treating acquired immunodeficiency syndrome or the human immunodeficiency virus as well as all reasonably priced generic prescription drugs on both PDLs.

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***PDL I.*** The bill requires DHFS to enter into rebate agreements with drug manufacturers by July 1, 2004, under which the manufacturers pay the supplemental rebates offered in response to DHFS solicitations on drugs that are included on PDL I and purchased under the state-supported health care assistance programs. Also by July 1, 2004, DHFS must implement at least one of the following policies to encourage use of PDL I under the state-supported health care assistance programs:

1. DHFS may require prior authorization for the purchase of any prescription drug that is not on PDL I; or

2. DHFS may monitor the prescribing practices of doctors, advanced practice nurses, and dentists to identify those practitioners who routinely prescribe drugs that are not on PDL I without medical justification and request that the applicable examining board, such as the Medical Examining Board, require the practitioner to participate in an education program on using the PDL.

Under the bill, manufacturers pay the supplemental rebates on drugs purchased under the state-supported health care assistance programs to DHFS. DHFS must allocate the supplemental rebate receipts to each of the state-supported health care assistance programs in the proportion in which they were earned.

***PDL II.*** The bill allows DHFS to phase in use of PDL II by enrollees in the Prescription Drug Assistance Program and beneficiaries of health care plans for government employees, private employees, and persons who purchase health insurance coverage individually. To earn the rebates offered by manufacturers whose drugs are included on PDL II, the provider or purchaser of a health care plan must adopt policies that encourage use of the PDL, such as prior authorization requirements or higher copayments for drugs that are not on the PDL, or mandatory PDL education for practitioners who prescribe drugs that are not on the PDL without medical justification.

The state may adopt policies to encourage use of PDL II by nonrepresented state employees at any time. The state may not require represented state employees to adhere to policies to encourage use of PDL II unless the employees agree to such policies through collective bargaining.

A local government, private employer, or entity that negotiates health care coverage for a group of individuals is not eligible to earn the rebates under PDL II unless DHFS approves the policies that the local government, private employer, or entity has adopted to encourage use of the PDL. A local governmental unit may not adopt policies that encourage use of the PDL by represented employees, unless those employees agree to the policies through collective bargaining.

Under the bill, manufacturers pay the supplemental rebates on drugs purchased under health care plans for state employees and under the Prescription Drug Assistance Program to the state. DHFS must designate the recipients of rebates paid under health care plans for local government employees, employees of private employers, and other private group plans.

***Prescription Drug Assistance Program***

The bill creates a program under which Wisconsin residents who do not have health insurance that covers prescription drugs (except a Medigap policy) may

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purchase prescription drugs for prices that are established by DHFS. DHFS must issue a Prescription Drug Assistance Program enrollment card to each person who applies for the program, meets the eligibility requirements, and pays an annual enrollment fee. A person who has a prescription drug card and a prescription order written by a practitioner who is licensed in Wisconsin is entitled to purchase prescription drugs from a participating pharmacy or pharmacist for the amounts established by DHFS. Any pharmacy or pharmacist that is licensed in any state within the United States and that agrees to sell drugs to program enrollees for the amounts established by DHFS may participate in the Prescription Drug Assistance Program.

If a program enrollee purchases a prescription drug that is included on PDL II (described above) and for which the manufacturer has entered into a rebate agreement with DHFS, a participating pharmacy or pharmacist may not charge the person an amount that is greater than the maximum price and dispensing fee established by DHFS minus the rebate. The drug manufacturer must pay DHFS the rebate amount on the drug, and DHFS must reimburse the pharmacy or pharmacist the rebate amount.

The bill appropriates child welfare income augmentation funds, subject to the approval of the Joint Committee on Finance, to make initial drug rebate reimbursements to participating pharmacies and pharmacists.

***Prescription drug manufacturer gift reporting***

The bill requires drug manufacturers to report annually to the Pharmacy Examining Board gifts that the manufacturers make to the following people in connection with marketing or promotional activities: practitioners who may prescribe drugs in Wisconsin; pharmacists; owners and operators of pharmacies; hospitals, nursing homes, or organizations that offer health benefit plans, or employees of hospitals, nursing homes, or such organizations. Manufacturers must report the value, nature, and purpose of any gift that is valued at \$25 or more, except that manufacturers are not required to report the provision of free drug samples that are intended to be distributed to patients. A manufacturer who violates the reporting requirements is subject to a \$10,000 forfeiture for each violation. The Pharmacy Examining Board must annually report to the legislature on gift disclosures made by drug manufacturers.

***HIRSP***

The bill also grants DHFS authority, independent of the PDL provisions, to negotiate rebate agreements with drug manufacturers on prescription drugs that are purchased under HIRSP.

For further information see the *state* fiscal estimate, which will be printed as an appendix to this bill.

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***The people of the state of Wisconsin, represented in senate and assembly, do enact as follows:***

1           **SECTION 1.** 20.435 (4) (jg) of the statutes is created to read:

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1           20.435 (4) (jg) *Prescription drug assistance; enrollment fees.* All moneys  
2 received from the payment of enrollment fees under s. 49.692 (3), to be used for  
3 administration of the program under s. 49.692.

4           **SECTION 2.** 20.435 (4) (jh) of the statutes is created to read:

5           20.435 (4) (jh) *Health insurance risk-sharing plan; drug manufacturer rebates.*  
6 All moneys received from rebate payments by manufacturers under s. 149.14 (4c) (c),  
7 to pay a portion of the operating costs of the health insurance risk-sharing plan  
8 under ch. 149.

9           **SECTION 3.** 20.435 (4) (jt) of the statutes is created to read:

10           20.435 (4) (jt) *Preferred drug lists.* All moneys received from the payment of  
11 fees under ss. 49.69 (6) (d) and 448.075 (2) to be used for administration of the  
12 preferred drug lists created under s. 49.69 (4).

13           **SECTION 4.** 20.435 (4) (jx) of the statutes is created to read:

14           20.435 (4) (jx) *Supplemental rebates on prescription drugs.* All moneys  
15 received from rebate payments by manufacturers and labelers under s. 49.69 (5) and  
16 (6) to provide Medical Assistance Program benefits administered under s. 49.45; to  
17 be used for the Badger Care health care program for low-income families under s.  
18 49.665; to pay pharmacies and pharmacists under s. 49.688 (7) for prescription drug  
19 assistance for elderly persons; to assist victims of disease, as provided in ss. 49.68,  
20 49.683, and 49.685; to pay a portion of the operating costs of the health insurance  
21 risk-sharing plan under ch. 149; to purchase primary health care services under s.  
22 146.93; to reimburse pharmacies and pharmacists under s. 49.692 (6); and to be  
23 credited to the public employee trust fund. The amounts expended under this  
24 paragraph shall be allocated as provided under s. 49.69 (7).

**ASSEMBLY BILL 355****SECTION 5**

1           **SECTION 5.** 20.435 (8) (mb) of the statutes, as affected by 2001 Wisconsin Act  
2 16, is amended to read:

3           20.435 (8) (mb) *Income augmentation services receipts.* All moneys that are  
4 received under 42 USC 670 to 679a, 42 USC 1395 to 1395ddd, and 42 USC 1396 to  
5 1396v as the result of income augmentation activities for which the state has  
6 contracted and all moneys that are received under 42 USC 1396 to 1396v in  
7 reimbursement of the cost of providing targeted case management services to  
8 children whose care is not eligible for reimbursement under 42 USC 670 to 679a, to  
9 be used as provided in s. 46.46 and 2003 Wisconsin Act .... (this act), section 25 (3).  
10 All moneys received under this paragraph in excess of the moneys necessary to  
11 support the costs specified in s. 46.46 and 2003 Wisconsin Act .... (this act), section  
12 25 (3), shall be deposited in the general fund as a nonappropriated receipt.

13           **SECTION 6.** 20.435 (8) (mb) of the statutes, as affected by 2001 Wisconsin Act  
14 16 and 2003 Wisconsin Act .... (this act), is amended to read:

15           20.435 (8) (mb) *Income augmentation services receipts.* All moneys that are  
16 received under 42 USC 670 to 679a, 42 USC 1395 to 1395ddd, and 42 USC 1396 to  
17 1396v as the result of income augmentation activities for which the state has  
18 contracted and all moneys that are received under 42 USC 1396 to 1396v in  
19 reimbursement of the cost of providing targeted case management services to  
20 children whose care is not eligible for reimbursement under 42 USC 670 to 679a, to  
21 be used as provided in s. 46.46 and 2003 Wisconsin Act .... (this act), section 25 (3).  
22 All moneys received under this paragraph in excess of the moneys necessary to  
23 support the costs specified in s. 46.46 and 2003 Wisconsin Act .... (this act), section  
24 25 (3), shall be deposited in the general fund as a nonappropriated receipt.

25           **SECTION 7.** 40.03 (6) (k) of the statutes is created to read:

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1           40.03 (6) (k) Upon request of the secretary of the department of health and  
2 family services, shall adopt policies that encourage use of the preferred drug list  
3 created under s. 49.69 (4) (a) 2. for group health insurance plans offered to state  
4 employees, except that for state employees covered by a collective bargaining  
5 agreement under subch. I or V of ch. 111 the board may adopt such policies that  
6 encourage use of the preferred drug list only if permitted under the collective  
7 bargaining agreement.

8           **SECTION 8.** 49.45 (49) of the statutes is repealed and recreated to read:

9           49.45 (49) PRESCRIPTION DRUG PRIOR AUTHORIZATION COMMITTEE. (a) The  
10 secretary shall exercise his or her authority under s. 15.04 (1) (c) to create a  
11 prescription drug prior authorization committee to do all of the following:

12           1. Advise the department on issues related to prior authorization decisions  
13 made concerning prescription drugs on behalf of Medical Assistance recipients.

14           2. Determine the relative clinical efficacy and safety of prescription drugs for  
15 the purpose of creating preferred drug lists as required under s. 49.69 (2).

16           (b) The secretary shall appoint as members of the prescription drug prior  
17 authorization committee at least the following:

18           1. Two physicians, as defined in s. 448.01 (5), who are currently in practice.

19           2. Two pharmacists, as defined in s. 450.01 (15).

20           3. One advocate for recipients of Medical Assistance who has sufficient medical  
21 background, as determined by the department, to evaluate the relative and clinical  
22 efficacy and safety of a prescription drug.

23           4. For the purpose of making determinations under s. 49.69 (2) regarding the  
24 relative clinical efficacy and safety of prescription drugs within a particular

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1 therapeutic class, persons who have medical expertise with respect to the disease or  
2 medical condition that the prescription drugs are intended to treat.

3 (c) A member of the prescription drug prior authorization committee may not  
4 be employed by or be a party to a contract with a manufacturer, as defined in s. 450.01  
5 (12), a distributor, as defined in s. 450.01 (9), or a labeler, as defined in s. 49.69 (1)

6 (d). Each committee member shall disclose any potential conflicts of interest related  
7 to an issue on which the committee acts and shall disclose the receipt of grant funding  
8 within the previous 36 months from a manufacturer, distributor, or labeler or  
9 ownership of stock in a manufacturer, distributor, or labeler. A member may not vote  
10 on an item if the member or the member's employer has a conflict of interest in the  
11 outcome of the vote. A member who may not vote on an item due to conflict of interest  
12 may participate in discussions related to the item.

13 (d) Notwithstanding the requirement under s. 15.04 (1) (c) that members of  
14 committees serve without compensation, members of the prescription drug prior  
15 authorization committee who are not officers or employees of this state shall be paid  
16 \$100 for each day on which they are actually and necessarily engaged in performance  
17 of their duties.

18 (e) The prescription drug prior authorization committee shall accept  
19 information or commentary from representatives of the pharmaceutical  
20 manufacturing industry and from consumer advocates in the committee's review of  
21 prior authorization policies and in its determinations regarding the relative clinical  
22 efficacy and safety of prescription drugs.

23 **SECTION 9.** 49.68 (3) (b) of the statutes is amended to read:

24 49.68 (3) (b) From the appropriation accounts under ss. 20.435 (4) (e) ~~and~~, (je),  
25 and (jx) the state shall pay the cost of medical treatment required as a direct result



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1 of chronic renal disease of certified patients from the date of certification, including  
2 the cost of administering recombinant human erythropoietin to appropriate  
3 patients, whether the treatment is rendered in an approved facility in the state or  
4 in a dialysis or transplantation center which is approved as such by a contiguous  
5 state, subject to the conditions specified under par. (d). Approved facilities may  
6 include a hospital in-center dialysis unit or a nonhospital dialysis center which is  
7 closely affiliated with a home dialysis program supervised by an approved facility.  
8 Aid shall also be provided for all reasonable expenses incurred by a potential  
9 living-related donor, including evaluation, hospitalization, surgical costs and  
10 postoperative follow-up to the extent that these costs are not reimbursable under the  
11 federal medicare program or other insurance. In addition, all expenses incurred in  
12 the procurement, transportation, and preservation of cadaveric donor kidneys shall  
13 be covered to the extent that these costs are not otherwise reimbursable. All  
14 donor-related costs are chargeable to the recipient and reimbursable under this  
15 subsection.

16 **SECTION 10.** 49.683 (2) of the statutes is amended to read:

17 49.683 (2) Approved costs for medical care under sub. (1) shall be paid from the  
18 appropriation accounts under s. 20.435 (4) (e) ~~and, (je), and (jx).~~

19 **SECTION 11.** 49.685 (2) of the statutes is amended to read:

20 49.685 (2) ASSISTANCE PROGRAM. From the appropriation accounts under s.  
21 20.435 (4) (e) ~~and, (je), and (jx)~~ the department shall establish a program of financial  
22 assistance to persons suffering from hemophilia and other related congenital  
23 bleeding disorders. The program shall assist such persons to purchase the blood  
24 derivatives and supplies necessary for home care. The program shall be  
25 administered through the comprehensive hemophilia treatment centers.

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1           **SECTION 12.** 49.688 (7) (a) of the statutes is amended to read:

2           49.688 (7) (a) Except as provided in par. (b), from the appropriation accounts  
3 under s. 20.435 (4) (bv) and, (j), ~~beginning on September 1, 2002, and (jx)~~ the  
4 department shall, under a schedule that is identical to that used by the department  
5 for payment of pharmacy provider claims under medical assistance, provide to  
6 pharmacies and pharmacists payments for prescription drugs sold by the  
7 pharmacies or pharmacists to persons eligible under sub. (2) who have paid the  
8 deductible specified under sub. (3) (b) 1. or 2. or who, under sub. (3) (b) 1., are not  
9 required to pay a deductible. The payment for each prescription drug under this  
10 paragraph shall be at the program payment rate, minus any copayment paid by the  
11 person under sub. (5) (a) 2. or 4., and plus, if applicable, incentive payments that are  
12 similar to those provided under s. 49.45 (8v). The department shall devise and  
13 distribute a claim form for use by pharmacies and pharmacists under this paragraph  
14 and may limit payment under this paragraph to those prescription drugs for which  
15 payment claims are submitted by pharmacists or pharmacies directly to the  
16 department. The department may apply to the program under this section the same  
17 utilization and cost control procedures that apply under rules promulgated by the  
18 department to medical assistance under subch. IV of ch. 49.

19           **SECTION 13.** 49.69 of the statutes is created to read:

20           **49.69 Preferred drug lists; prescription drug cost containment. (1)** In  
21 this section:

22           (a) "Committee" means the prescription drug prior authorization committee  
23 created under s. 49.45 (49).

24           (b) "Generic name" has the meaning given in s. 450.12 (1) (b).

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1 (c) "Health care coverage plan for government employees" means a health care  
2 coverage plan offered by the state or by a local governmental unit to its employees.

3 (d) "Labeler" means a person that receives prescription drugs from a  
4 manufacturer or wholesaler and repackages those drugs for later retail sale, and has  
5 a labeler code issued by the federal food and drug administration under 21 CFR  
6 207.20 (b).

7 (e) "Local governmental unit" means a political subdivision of this state, a  
8 special purpose district in this state, an instrumentality or corporation of the  
9 political subdivision or special purpose district or a combination or subunit of any of  
10 the foregoing.

11 (f) "Manufacturer" means a person engaged in the production, preparation,  
12 propagation, compounding, conversion, or processing of prescription drugs.

13 (g) "Off-list prescription drug" means a prescription drug that is not included  
14 on the applicable preferred drug list created under sub. (4).

15 (h) "Practitioner" has the meaning given in s. 450.01 (17).

16 (i) "Prescription drug" has the meaning given in s. 450.01 (20).

17 (j) "Prescription Drug Assistance Program" means the program under s.  
18 49.692.

19 (k) "Private health care coverage plan" means a health care coverage plan  
20 offered by a private employer to its employees or a health care coverage plan, other  
21 than a health care coverage plan for government employees, that is negotiated on  
22 behalf of a group of individuals who individually purchase coverage under the plan.

23 (L) "Single-source prescription drug" means a prescription drug that is  
24 produced or distributed under an original new drug application approved by the  
25 federal food and drug administration under 21 USC 355.

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1 (m) "State-supported health care assistance program" means the Medical  
2 Assistance Program or the program under s. 49.665, 49.68, 49.683, 49.685, 49.688,  
3 or 146.93 or ch. 149.

4 (n) "Therapeutic class" means a class of prescription drugs that are intended  
5 to treat the same disease or medical condition by substantially similar biochemical  
6 and physiological mechanisms.

7 **(2)** (a) By January 1, 2004, the committee shall determine the relative clinical  
8 efficacy and safety of the prescription drugs within each therapeutic class. The  
9 committee shall conduct an evidence-based analysis to determine the relative  
10 clinical efficacy and safety, including a review of relevant literature. The committee  
11 shall periodically review and amend its determinations of relative clinical efficacy  
12 and safety.

13 (b) Notwithstanding par. (a), the committee may adopt determinations of  
14 relative clinical efficacy and safety made by a similar governmental entity in another  
15 state, if the other entity uses standards for determining clinical efficacy and safety  
16 that are similar to the standards adopted by the committee.

17 (c) The committee shall make a determination regarding the relative clinical  
18 efficacy and safety of a new single-source prescription drug within 60 days after it  
19 is approved by the federal food and drug administration or, if the committee does not  
20 receive sufficient information to make a determination within 60 days after  
21 approval, within 60 days after receiving such information.

22 **(3)** (a) The department shall solicit bids or proposals from manufacturers and  
23 labelers to provide rebates on prescription drugs that are purchased under  
24 state-supported health care assistance programs. Any rebate offered by a  
25 manufacturer or labeler in response to a solicitation under this paragraph shall be

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1 in addition to any rebate that the manufacturer or labeler provides under 42 USC  
2 1396r-8 and in addition to any rebate required under state law or provided under  
3 an agreement between the state and a manufacturer or labeler that is in effect on the  
4 effective date of the solicitation.

5 (b) Subject to sub. (8), the department shall solicit bids or proposals from  
6 manufacturers and labelers to provide rebates on prescription drugs that are  
7 purchased under the Prescription Drug Assistance Program, under health care  
8 coverage plans for government employees, or under private health care coverage  
9 plans.

10 (c) The department may join with similar governmental entities in other states  
11 to solicit rebates under this subsection.

12 (4) (a) Using the method prescribed under par. (b) the department shall create  
13 the following 2 preferred drug lists:

- 14 1. One preferred drug list for state-supported health care assistance programs.
- 15 2. A 2nd preferred drug list for the Prescription Drug Assistance Program,  
16 health care coverage plans for government employees, and private health care  
17 coverage plans.

18 (b) The department shall consider the relative clinical efficacy and safety and  
19 the cost of each prescription drug in a therapeutic class, and place the most  
20 cost-effective prescription drug or drugs in the class on a preferred drug list. In  
21 determining cost under this paragraph, the department shall consider any rebate  
22 offered under sub. (3) (a) or (b), whichever is applicable, any existing rebate  
23 agreement or requirement, dosing practices, and any other relevant cost  
24 information.

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1 (c) Notwithstanding par. (b), the department shall include all prescription  
2 drugs that the committee determines are clinically effective and safe for treating  
3 acquired immunodeficiency syndrome or the human immunodeficiency virus on both  
4 preferred drug lists created under this subsection. The department shall also  
5 include all prescription drugs that bear generic names on the preferred drug lists  
6 unless the prescription drugs that bear generic names are unreasonably priced  
7 compared to other prescription drugs within a therapeutic class that are selected for  
8 a preferred drug list.

9 (5) By July 1, 2004, the department shall enter into agreements with the  
10 manufacturers or labelers of the prescription drugs on the preferred drug list under  
11 sub. (4) (a) 1. to pay the state the rebates proposed under sub. (3) (a) on prescription  
12 drugs that are purchased under state-supported health care assistance programs on  
13 or after July 1, 2004.

14 (6) (a) Subject to sub. (8), the department shall enter into agreements with the  
15 manufacturers or labelers of prescription drugs on the preferred drug list under sub.  
16 (4) (a) 2. to pay the rebates proposed under sub. (3) (b) on prescription drugs that are  
17 purchased under the following programs or plans:

18 1. The Prescription Drug Assistance Program.

19 2. Health care coverage plans offered by the state to state employees who are  
20 not subject to collective bargaining.

21 3. Health care coverage plans offered by the state to state employees who are  
22 subject to collective bargaining, if the employees agree through collective bargaining  
23 to subject their health care coverage to policies that encourage use of the preferred  
24 drug list under sub. (4) (a) 2.

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1           4. Health care coverage plans offered by a local governmental unit to employees  
2 of the local governmental unit who are subject to collective bargaining, if the  
3 employees agree through collective bargaining to subject their health care coverage  
4 to policies that encourage use of the preferred drug list under sub. (4) (a) 2.

5           5. Health care coverage plans offered by a local governmental unit to its  
6 employees who are not subject to collective bargaining or private health care  
7 coverage plans, if the department approves the plan, or the employment contract  
8 that provides for the plan under par. (b).

9           (b) An entity that purchases or negotiates health insurance coverage for  
10 employees of a local governmental unit or that purchases or negotiates a private  
11 health care coverage plan may apply to the department to approve a health care  
12 coverage plan, or an employment contract that provides for health care coverage.  
13 The department shall approve the plan or contract if it includes policies to encourage  
14 use of the preferred drug list under sub. (4) (a) 2.

15           (c) For purposes of this section, all of the following constitute policies to  
16 encourage use of the preferred drug list under sub. (4) (a) 2.:

17           1. Prior authorization for off-list prescription drugs.

18           2. Higher copayments for off-list prescription drugs than for drugs that are on  
19 the preferred drug list.

20           3. Education for practitioners who prescribe off-list prescription drugs without  
21 medical justification.

22           (d) The department shall charge entities that receive rebates under par. (a) 4.  
23 or 5. a fee to support the administrative costs of creating and maintaining the  
24 preferred drug lists under sub. (4). The department shall promulgate rules  
25 establishing the method for determining the amount of the fee. All fees collected

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1 under this paragraph shall be credited to the appropriation account under s. 20.435  
2 (4) (jt).

3 (e) Manufacturers and labelers shall pay rebates under par. (a) 1., 2., and 3.,  
4 to the state, and shall pay rebates under par. (a) 4. and 5. to the entity designated  
5 by the department.

6 (7) All rebates paid to the state under subs. (5) and (6) (a) 1., 2., and 3. shall  
7 be credited to the appropriation account under s. 20.435 (4) (jx). The department  
8 shall calculate the amount of rebates earned on prescription drugs purchased under  
9 each of the state-supported health care assistance programs, under the Prescription  
10 Drug Assistance Program, and under health care coverage plans for state employees,  
11 and shall allocate the amount earned under each program or plan for that program  
12 or plan.

13 (8) The department shall determine when to cover each of the programs or  
14 plans under sub. (6) (a) 1., 2., 3., 4., and 5. in solicitations under sub. (3) (b) and in  
15 agreements under sub. (6) (a).

16 (9) (a) By July 1, 2004, the department shall implement at least one of the  
17 following prescription drug cost containment measures using the preferred drug list  
18 created under sub. (4) (a) 1.:

19 1. The department may require practitioners to obtain prior authorization from  
20 the department or its fiscal agent for any off-list prescription drug purchased under  
21 a state-supported health care assistance program and may prohibit reimbursement  
22 of pharmacists, pharmacies, or any other provider for any off-list prescription drug  
23 purchased under a state-supported health care assistance program for which prior  
24 authorization is not obtained. If the department requires prior authorization under  
25 this subdivision, and a practitioner requests prior authorization for an off-list



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1 prescription drug, the department or its fiscal agent shall respond to the request by  
2 telephone or other telecommunication means within 24 hours after the request is  
3 received. In an emergency situation, the department shall reimburse a pharmacy  
4 or pharmacist for at least a 7-day supply of a prescription without prior  
5 authorization.

6 2. The department may monitor the purchase of prescription drugs under  
7 state-supported health care assistance programs to identify practitioners who  
8 routinely prescribe off-list prescription drugs without medical justification and  
9 request that the medical examining board, board of nursing, or dentistry examining  
10 board, whichever is applicable, investigate and, if appropriate, require education for  
11 such practitioners under s. 441.16 (7), 447.08, or 448.075, whichever is applicable.

12 (b) The department may monitor the purchase of prescription drugs under the  
13 Prescription Drug Assistance Program to identify practitioners who routinely  
14 prescribe off-list prescription drugs without medical justification and request that  
15 the medical examining board, board of nursing, or dentistry examining board,  
16 whichever is applicable, investigate and, if appropriate, require education for such  
17 practitioners under s. 441.16 (7), 447.08, or 448.075, whichever is applicable.

18 **(10)** (a) The department may enter into a contract with an entity to perform  
19 the duties and exercise the powers of the department, other than promulgation of  
20 rules, under subs. (3), (4), (5), and (6).

21 (b) The department may not contract under this subsection with an entity if the  
22 entity, its parent company, or its subsidiary has any direct or indirect financial  
23 interest in sales of a particular prescription drug. The department shall require an  
24 entity to disclose all such financial interests before the department contracts with  
25 the entity under this subsection.

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1 (c) An entity that enters into a contract with the department under this  
2 subsection, or a parent company or subsidiary of that entity, may not incur a financial  
3 interest in sales of a particular prescription drug during the term of the contract.

4 (d) The department shall periodically audit any entity with which it contracts  
5 under this subsection to determine whether the entity, its parent company, or a  
6 subsidiary has any financial interests that are prohibited under this subsection.

7 **SECTION 14.** 49.692 of the statutes is created to read:

8 **49.692 Prescription drug assistance. (1)** In this section:

9 (a) “Labeler” has the meaning given in s. 49.69 (1) (d).

10 (b) “Manufacturer” has the meaning given in s. 49.69 (1) (f).

11 (c) “Participating pharmacy or pharmacist” means a person who is licensed as  
12 a pharmacy or pharmacist in any state and who agrees to sell prescription drugs to  
13 a person who has a prescription drug card issued under sub. (3) for the amount  
14 provided under sub. (5).

15 (d) “Prescription drug” has the meaning given in s. 450.01 (20).

16 (e) “Prescription order” has the meaning given in s. 450.01 (21).

17 (f) “State” has the meaning given in s. 441.50 (2) (m).

18 **(2)** (a) A person to whom all of the following applies is eligible to purchase  
19 prescription drugs from a participating pharmacy or pharmacist for the amount  
20 provided under sub. (5):

21 1. The person is a resident, as defined in s. 27.01 (10) (a), of this state.

22 2. The person is not a recipient of Medical Assistance, does not have health care  
23 coverage under s. 49.665, does not have a policy issued under ch. 149, is not enrolled  
24 in the program under s. 49.688, and does not have insurance coverage for  
25 prescription drugs for outpatient care, except that a person who receives benefits

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1 under 42 USC 1395 to 1395ccc may have supplemental health insurance that covers  
2 prescription drugs for outpatient care.

3 (b) A person may apply to the department, on a form provided by the  
4 department, for a determination of eligibility and issuance of a prescription drug  
5 card for purchase of prescription drugs under this section.

6 (3) The department shall devise and distribute a form for applying for the  
7 program under sub. (2), shall determine eligibility for each 12-month benefit period  
8 of applicants, and, after payment by the applicant of a program enrollment fee for  
9 each 12-month benefit period, shall issue to eligible persons a prescription drug card  
10 for use in purchasing prescription drugs, as provided under this section.

11 (4) The department shall set maximum prices and a maximum dispensing fee  
12 for prescription drugs purchased under this section.

13 (5) Beginning September 1, 2004, a participating pharmacy or pharmacist may  
14 not charge a person who presents a valid prescription order and a prescription drug  
15 card issued under sub. (3) more than the maximum price established by the  
16 department under sub. (4) for a prescription drug, less any rebate amount agreed to  
17 under s. 49.69 (6) (a) 1., plus the maximum dispensing fee established by the  
18 department under sub. (4).

19 (6) From the appropriation account under s. 20.435 (4) (jx) and (8) (mb), the  
20 department shall reimburse participating pharmacies and pharmacists the  
21 applicable rebate amounts specified in agreements under s. 49.69 (6) (a) 1., if any, for  
22 each prescription drug that the pharmacy or pharmacist sells to a person who has  
23 a prescription drug card issued under sub. (3).

24 (7) The department shall promulgate rules establishing the following:

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1 (a) The method for determining the maximum retail price for a prescription  
2 drug.

3 (b) The method for determining the maximum dispensing fee.

4 (c) The method for informing participating pharmacies and pharmacists of the  
5 maximum prices, dispensing fees, and rebate amounts for prescription drugs.

6 (d) The process by which a participating pharmacy or pharmacist may claim  
7 reimbursement for rebates.

8 (e) The process for resolving discrepancies between the rebate amount claimed  
9 by a participating pharmacy or pharmacist and the amount paid by a manufacturer  
10 or labeler.

11 **SECTION 15.** 49.692 (6) of the statutes, as created by 2003 Wisconsin Act .... (this  
12 act), is amended to read:

13 49.692 (6) From the appropriation account under s. 20.435 (4) (jx) ~~and (8) (mb)~~,  
14 the department shall reimburse participating pharmacies and pharmacists the  
15 applicable rebate amounts specified in agreements under s. 49.69 (6) (a) 1., if any, for  
16 each prescription drug that the pharmacy or pharmacist sells to a person who has  
17 a prescription drug card issued under sub. (3).

18 **SECTION 16.** 146.93 (1) (a) of the statutes is amended to read:

19 146.93 (1) (a) From the ~~appropriation~~ appropriation accounts under s. 20.435  
20 (4) (gp) ~~and (jx)~~, the department shall maintain a program for the provision of  
21 primary health care services based on the primary health care program in existence  
22 on June 30, 1987. The department may promulgate rules necessary to implement  
23 the program.

24 **SECTION 17.** 149.14 (4c) (c) of the statutes is created to read:

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1           149.14 (4c) (c) The department or an entity with which the department  
2 contracts shall provide to a drug manufacturer that sells drugs for prescribed use in  
3 this state documents designed for use by the manufacturer in entering into a rebate  
4 agreement with the department or entity that is modeled on the rebate agreement  
5 specified under 42 USC 1396r-8. The department or entity may enter into a rebate  
6 agreement under this paragraph that shall include all of the following as  
7 requirements:

8           1. That, as a condition of coverage for prescription drugs of a manufacturer  
9 under this section other than prescription drugs that are prescribed for the  
10 treatment of acquired immunodeficiency syndrome or human immunodeficiency  
11 virus, the manufacturer shall make rebate payments for each prescription drug of  
12 the manufacturer, that is prescribed for and purchased by an eligible person, to the  
13 state treasurer to be credited to the appropriation account under s. 20.435 (4) (jh),  
14 each calendar quarter or according to a schedule established by the department.

15           2. That the amount of the rebate payment shall be determined by a method  
16 specified in 42 USC 1396r-8 (c).

17           **SECTION 18.** 149.143 (1) (a) of the statutes is amended to read:

18           149.143 (1) (a) First from the moneys transferred to the fund from the  
19 appropriation account under s. 20.435 (4) (af) and from the moneys appropriated for  
20 the health insurance risk-sharing plan under s. 20.435 (4) (jh) and (jx).

21           **SECTION 19.** 441.16 (7) of the statutes is created to read:

22           441.16 (7) Upon the request of the department of health and family services,  
23 the board shall investigate an advanced practice nurse to determine whether the  
24 advanced practice nurse routinely prescribes prescription drugs that are not on the  
25 applicable preferred drug list established under s. 49.69 to beneficiaries of

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1 state-supported health care assistance programs, as defined in s. 49.69 (1) (m), or  
2 to persons enrolled in the prescription drug assistance program under s. 49.692,  
3 without medical justification. If the board determines that an advanced practice  
4 nurse routinely prescribes drugs that are not on the applicable preferred drug list  
5 without medical justification, the board shall require the advanced practice nurse to  
6 complete the preferred drug list education program under s. 448.075 (2) at the  
7 earliest possible opportunity.

8 **SECTION 20.** 447.08 of the statutes is created to read:

9 **447.08 Preferred drug list compliance.** Upon the request of the  
10 department of health and family services, the board shall investigate a dentist to  
11 determine whether the dentist routinely prescribes prescription drugs that are not  
12 on the applicable preferred drug list established under s. 49.69 to beneficiaries of  
13 state-supported health care assistance programs, as defined in s. 49.69 (1) (m), or  
14 to persons enrolled in the Prescription Drug Assistance Program under s. 49.692,  
15 without medical justification. If the board determines that a dentist routinely  
16 prescribes drugs that are not on the applicable preferred drug list without medical  
17 justification, the board shall require the dentist to complete the preferred drug list  
18 education program under s. 448.075 (2) at the earliest possible opportunity.

19 **SECTION 21.** 448.075 of the statutes is created to read:

20 **448.075 Preferred drug list compliance. (1)** Upon the request of the  
21 department of health and family services, the board shall investigate a physician or  
22 physician assistant to determine whether the physician or physician assistant  
23 routinely prescribes prescription drugs that are not on the applicable preferred drug  
24 list established under s. 49.69 to beneficiaries of state-supported health care  
25 assistance programs, as defined in s. 49.69 (1) (m), or to persons enrolled in the

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1 Prescription Drug Assistance Program under s. 49.692, without medical  
2 justification. If the board determines that a physician or physician assistant  
3 routinely prescribes drugs that are not on the applicable preferred drug list without  
4 medical justification, the board shall require the physician or physician assistant to  
5 complete the preferred drug list education program under sub. (2) at the earliest  
6 possible opportunity.

7 (2) The department of regulation and licensing shall develop an education  
8 program on the preferred drug lists created under s. 49.69 for practitioners, as  
9 defined in s. 450.01 (17). The department of regulation and licensing shall consult  
10 with the department of health and family services in developing the education  
11 program and shall present the education program both as a class and in visits to  
12 practitioners' offices. The department of regulation and licensing shall charge  
13 practitioners who are required under sub. (1) or s. 441.16 (7) or 447.08 to participate  
14 in the education program to pay a fee to cover the cost of the class or office visit. All  
15 fees collected under this subsection shall be credited to the appropriation account  
16 under s. 20.435 (4) (jt).

17 **SECTION 22.** 450.02 (2) of the statutes is renumbered 450.02 (2) (intro.) and  
18 amended to read:

19 450.02 (2) (intro.) The board shall ~~adopt rules defining~~ promulgate all of the  
20 following rules, which apply to all applicants for licensure under s. 450.05:

21 (a) Defining the active practice of pharmacy. The rules shall apply to all  
22 applicants for licensure under s. 450.05.

23 **SECTION 23.** 450.02 (2) (b) of the statutes is created to read:

24 450.02 (2) (b) Requiring disclosure by a pharmacist to a prescription drug  
25 purchaser who has a card issued under s. 49.692 (3) of the amount of the discount

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1 on the retail price of the prescription drug that is provided to the purchaser as a  
2 result of the program under s. 49.692.

3 **SECTION 24.** 450.075 of the statutes is created to read:

4 **450.075 Manufacturer gift reporting. (1)** In this section:

5 (a) “Health benefit plan” has the meaning given in s. 632.745 (11).

6 (b) “Hospital” means a facility approved as a hospital under s. 50.35.

7 (c) “Nursing home” has the meaning given in s. 50.01 (3).

8 **(2)** (a) Except as provided in par. (c), each person who engages in  
9 manufacturing shall annually report to the board the value, nature, and purpose of  
10 any gift, payment, subsidy, or other economic benefit valued at \$25 or more that the  
11 person directly or indirectly provides to any of the following in connection with the  
12 person’s promotional or marketing activities:

13 1. A practitioner.

14 2. A pharmacist or an owner or operator of a pharmacy.

15 3. A hospital, nursing home, or organization that offers a health benefit plan,  
16 or an employee of a hospital, nursing home, or organization that offers a health  
17 benefit plan.

18 4. Any other person authorized to purchase prescription drugs for retail or  
19 wholesale resale.

20 (b) A person who engages in manufacturing shall submit the report required  
21 under par. (a) by January 1 of each year for the 12-month period ending on the  
22 previous June 30.

23 (c) A person who engages in manufacturing is not required to report under par.  
24 (a) any free sample of a prescription drug that is intended to be distributed to a  
25 patient.



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1           **(3)** Each person who engages in manufacturing shall report to the board the  
2 name and address of the individual responsible for making reports under sub. (2) and  
3 shall notify the board of any change in the information required under this  
4 subsection.

5           **(4)** A person who engages in manufacturing who violates sub. (2) may be  
6 required to forfeit not more than \$10,000 for each violation and, notwithstanding s.  
7 814.04, to pay all actual costs incurred by the state in prosecuting the violation,  
8 including reasonable attorney fees.

9           **(5)** The board shall develop a form that persons who engage in manufacturing  
10 shall use to submit reports under sub. (2).

11           **(6)** Any information reported under this section that constitutes a trade secret,  
12 as defined in s. 134.90 (1) (c), shall remain confidential. The board may not release  
13 trade secret information obtained under this section, except to the department of  
14 justice for the purpose of prosecuting a violation under sub. (4). The form prescribed  
15 by the board under sub. (5) shall direct a person who engages in manufacturing to  
16 identify any information that is a trade secret.

17           **(7)** Annually, by March 1, the board shall submit to the legislature under s.  
18 13.172 (2) and to the governor a report describing the disclosures made under sub.  
19 (2).

20           **SECTION 25. Nonstatutory provisions.**

21           **(1) ENROLLMENT FEE FOR PRESCRIPTION DRUG ASSISTANCE PROGRAM.** The  
22 enrollment fee for the prescription drug assistance program under section 49.692 (3)  
23 of the statutes, as created by this act, shall be \$20, except that the department of  
24 health and family services shall review the costs to administer the prescription drug  
25 assistance program after it has been implemented for 12 months and shall reduce

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1 the program enrollment fee if the earnings from the fee are greater than the costs  
2 incurred by the department in administering the program.

3 (2) REPORT TO LEGISLATURE. By July 1, 2006, the department of health and  
4 family services shall report to the appropriate standing committees of the  
5 legislature, in the manner provided under section 13.172 (3) of the statutes, on the  
6 creation of preferred drug lists, the status of supplemental prescription drug rebate  
7 agreements, and the implementation of prescription drug cost controls under section  
8 49.69 of the statutes, as created by this act.

9 (3) USE OF INCOME AUGMENTATION RECEIPTS FOR INITIAL REIMBURSEMENT TO  
10 PHARMACISTS AND PHARMACIES. If after supporting the costs specified in section 46.46  
11 of the statutes, there remain any moneys in the appropriation account under section  
12 20.435 (8) (mb) of the statutes, as affected by this act, those remaining moneys are  
13 allocated to the department of health and family services to reimburse pharmacies  
14 and pharmacists under section 49.692 (6) of the statutes, as created by this act, until  
15 such time as there is enough money in the account under section 20.435 (4) (jx) of the  
16 statutes, as created by this act, to make timely reimbursement payments to  
17 pharmacies and pharmacists under section 49.692 (6) (a) of the statutes, as created  
18 by this act. The department of health and family services may not expend or  
19 encumber any moneys allocated under this subsection unless the department  
20 submits a plan for the proposed use of those moneys to the secretary of  
21 administration. If the secretary of administration approves the plan, he or she shall  
22 submit the plan to the joint committee on finance. If the cochairpersons of the  
23 committee do not notify the secretary of administration within 14 working days after  
24 the date of the secretary's submittal of the plan that the committee has scheduled a  
25 meeting for the purpose of reviewing the plan, the department of health and family

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1 services may implement the plan as proposed by the department of health and family  
2 services and approved by the secretary of administration. If, within 14 working days  
3 after the date of the secretary's submittal, the cochairpersons of the committee notify  
4 the secretary that the committee has scheduled a meeting for the purpose of  
5 reviewing the plan, the department of health and family services may implement the  
6 plan only upon the approval of the committee.

7 (4) EMERGENCY RULES. The department of health and family services shall,  
8 using the procedure under section 227.24 of the statutes, promulgate the rules  
9 required under section 49.692 (7) of the statutes, as created by this act, for the period  
10 before permanent rules become effective, but not to exceed the period authorized  
11 under section 227.24 (1) (c) and (2) of the statutes. Notwithstanding section 227.24  
12 (1) (a), (2) (b), and (3) of the statutes, the department is not required to provide  
13 evidence that promulgating a rule under this subsection as an emergency rule is  
14 necessary for the preservation of the public peace, health, safety, or welfare and is  
15 not required to provide a finding of emergency for a rule promulgated under this  
16 subsection.

17 **SECTION 26. Effective dates.** This act takes effect on the day after publication,  
18 on the 2nd day after publication of the 2003-05 biennial budget act, or on July 1,  
19 2003, whichever is later, except as follows:

20 (1) The treatment of sections 20.435 (8) (mb) (by SECTION 6) and 49.692 (6) (by  
21 SECTION 15) of the statutes takes effect on July 1, 2005.

22 (END)